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March 2, 2015

VIA UNITED STATES MAIL

Dr. George Alexeeff, Director
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT
1001 I Street
Sacramento, California 95812-4010

RE: HAZARD IDENTIFICATION MATERIALS SUBMITTED TO DEVELOPMENTAL AND REPRODUCTIVE TOXICANT IDENTIFICATION COMMITTEE REGARDING BISPHENOL A

Dear Dr. Alexeeff:

We are writing on behalf of our client the Polycarbonate/Bisphenol A Global Group of the American Chemistry Council ("ACC") regarding OEHHA's February 20, 2015 Announcement that the Developmental and Reproductive Toxicant Identification Committee ("DARTIC") will convene on May 7 (and possibly May 21) 2015 to consider whether to designate Bisphenol A ("BPA") as a "chemical known to cause reproductive toxicity" for purposes of Proposition 65.

According to the Announcement, the public and interested parties are being provided forty-five days from the date of the Announcement to submit comments, such that comments from ACC to explain why BPA should not be so designated are due no later than April 6, 2015, one month before the May 7 DARTIC meeting. Without prejudice to that opportunity, we are writing now (a) to note that that the Hazard Identification Materials (or "HIM") are incomplete and should be supplemented promptly and (b) to suggest that it would be appropriate to extend the due date for public comments by two weeks until April 20, 2015, so that our client may prepare a document that summarizes and reviews the data appropriately. This extension is necessary in part because the HIM is incomplete; in part because it was not preceded by a Request for Relevant Information, as is usually the case; and in part because it is not accompanied by a comprehensive agency review of the data, as OEHHA traditionally provides.

Hazard Identification Materials. The Announcement indicates that OEHHA has gathered certain "epidemiological and toxicological data on BPA and female reproductive toxicity that have become available since 2009" (when the DARTIC voted unanimously not to designate BPA as a reproductive toxicant). The Announcement provides a link "announc[ing]

the availability of hazard identification materials on BPA and reproductive toxicity" and then indicates that the "DARTIC will consider" these "hazard identification materials" in "making any listing decision regarding this chemical."

A statement in the Introduction to the Hazard Identification Materials elaborates that OEHHA is submitting these materials to the DARTIC in response to the DARTIC's "request" on July 15, 2009, following its unanimous vote not to designate BPA as a developmental or reproductive toxicant, for the opportunity to revisit that determination if "additional epidemiological or other specific types of data on reproductive and developmental toxicity became available."[1] The document is entitled "Hazard Identification Materials for Consideration of the Female Reproductive Toxicity on Bisphenol A" and identifies certain materials that "are being provided to the DARTIC in electronic form." The principal documents among these materials are an August 2014 article by Peretz, *et al.*, published in Environmental Health Perspectives ("EHP"), which the HIM describes as a review of "new studies . . . conducted on the impact of BPA on reproduction . . . that have become available subsequent to the DARTIC's consideration of BPA in 2009;"[2] some "Supplemental Materials" to the same review; the articles cited in the EHP review; and certain unnamed studies "relevant to female reproductive toxicity."[3]

We believe these Hazard Identification Materials are significantly incomplete. While we don't believe that any of the data among the HIM would support listing, there at least two documents of fundamental importance that have been omitted from the HIM and should be sent to the DARTIC promptly:

- ***Scientific Opinion on the Risks to Public Health Related to the Presence of Bisphenol A (BPA) in Foodstuffs***, published by the European Food Safety Authority ("EFSA") on January 21, 2015, and available online at www.efsa.europa.eu/en/efsajournal/pub/3978.htm. This 1039-page assessment of the scientific literature on BPA includes a comprehensive review of studies conducted to evaluate the potential hazard of BPA for reproductive and developmental effects, including specifically most of the studies cited in the EHP review.

- ***2014 Updated Review of Literature and Data on Bisphenol A (CAS RN 80-05-7)*** published by the United States Food and Drug Administration on June 6, 2014 and available online at www.fda.gov/Food/IngredientsPackagingLabeling/

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1 The HIM are available online at http://oehha.org/prop65/hazard_ident/BPAhazardID2014.html

2 Peretz J., Vrooman L., Ricke W.A., Hunt P.A., Erlich S., Hauser R., Padmanbhan V., Taylor H.S., Swan S.H., VandeVoort C.A., and Flaws. J.A., Environmental Health Perspectives 122(8): 775-786 (2014)

3 The HIM also include as certain materials published before the July 15, 2009 DARTIC meeting and public comments submitted to the DARTIC before that meeting.

FoodAdditivesIngredients/ucm166145.htm. This memorandum completes a multiyear project of the FDA Bisphenol A Joint Emerging Science Working Group, and is accompanied by a 2012 Updated Review of Literature and Data on Bisphenol A (August 22, 2013) and an Updated Review of the 'Low-Dose' Literature (Data) on Bisphenol A and Response to Charge Questions regarding the Risk Assessment on Bisphenol A, which together constitute a comprehensive review of approximately 300 studies, including studies relevant to female reproductive toxicity, that were published or became available from November 1, 2009 to July 23, 2013. Like the EFSA Scientific Opinion, the FDA memorandum directly addresses many of the studies discussed in the EHP review.

Without a complete search of the literature (which ACC is conducting now), we cannot say that these are the only reports that were omitted from and should have been included in the HIM. While it bears repeating that the data in the HIM would not support listing, the absence of just these two evaluations renders the HIM incomplete, misleading and unfair. Without these reviews and potentially other studies, the HIM as presently constituted cannot serve legitimately as the basis for a decision, or as an administrative record that would support a decision to list, because the record is so incomplete. We thus request that the EFSA and FDA studies be provided to the DARTIC, with an indication from OEHHA that these studies should be reviewed along with other materials already provided by OEHHA in determining whether BPA should be listed.

Request for Extension of Time to Submit Comments. It is clear from the discussion above that the documents assembled as the HIM are incomplete. And to the extent that the principal "new" study, the EHP review, may point toward listing BPA, the HIM are misleading. Substantial work is required, therefore, first to analyze the EHP review, and then to analyze the studies reviewed in the EFSA Scientific Opinion, the FDA Updated Review, as well as the substantial body of scientific literature that has become available since 2009.

Under these circumstances, and particularly because OEHHA has not solicited the submission of data through a Request for Relevant Information, it would be appropriate for OEHHA to place the DARTIC proceeding in abeyance; to reformulate the HIM to include the EFSA Scientific Opinion, the FDA Updated review and potentially other documents as part of the HIM; and then to proceed in a more systematic fashion to present all of these materials to the DARTIC with comments from interested parties. If that is not to occur, then fairness requires more time in order that our client may assimilate these materials and present them systematically in written format to the panel before the DARTIC meeting. Indeed, recent controversies at public meetings of the DARTIC and its sister Carcinogen Identification Committee have demonstrated the difficulty in supplementing or correcting the toxicological record through oral presentations, and that a comprehensive written presentation is necessary to communicate with the experts on these Committees, giving them at least the opportunity to review all of the relevant data before a meeting is convened.

Thus, if OEHHA is disinclined to reschedule the consideration of BPA so that a complete HIM can be prepared, we would request at the very least that the time to prepare and submit written materials be extended from April 6 until April 20, 2015. This extended deadline still would allow the Committee members over two weeks to review the materials before the first day of the two-day meeting proposed. If more time is required for their review, then we suggest that initial proceedings on BPA could be held on May 21, which already has been scheduled as a potential meeting date.

In conclusion, both of these requests are reasonable to ensure a full and fair deliberation on BPA. The scientific record should be presented completely without the false urgency of an arbitrary deadline. We appreciate the effort that OEHHA takes to get issues before the Committees once hearing dates are set. Given the volume of studies on BPA and the volume of data that were omitted from the HIM, and the consensus among the regulatory agencies in jurisdictions other than California, it is appropriate to allow parties that oppose listing to ensure that the record is complete and that all relevant data are considered.

Very truly yours,

Christian Volz
Stanley W. Landfair
Counsel for the Polycarbonate/Bisphenol A Global Group of the American Chemistry Council

cc: Carol Monahan-Cummings (Chief Counsel)

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